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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NIEBAUER, RONALD T

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

01/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,996	Applicant(s) KRAHMER ET AL.	
	Examiner RONALD T. NIEBAUER	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 3-12 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,13,14 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendments and arguments filed 9/25/08 are acknowledged and have been fully considered. Applicant has added claim 21 and amended claims 1,2,6,7.

Any rejection and/or objection not specifically addressed is herein withdrawn. It is noted that applicant has provided arguments and a declaration with respect to the previous written description rejection (112 1st paragraph). The declaration alone is not persuasive as the declaration does not state when the experiments were undertaken and such experiments were not a part of the original application. However, the arguments are found convincing, briefly, due to the fact that the compounds require a core structure of either formula Ia or Ib. As such, the previous written description rejection is withdrawn.

It is noted that 2 different claim sets were entered on 9/25/08. The claim set with claim 21 added is the claim set under consideration.

37 CFR 1.121 (c)(2) states: ‘All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of “currently amended,” and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text.’

In the instant case Claim 1 of 9/13/07 stated ‘...Z together exhibit at least one group.....’. The claims dated 9/25/08 state ‘...Z together exhibit at least two groups....’. Although applicant has appropriately noted the amendment to the claim in other locations applicant neglected to

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properly mark claim 1 with respect to the change from 'one group' to 'two groups'. In order to advance prosecution the amendment has been considered.

As stated previously, the elected species, (of formula Ia where Z is formula Xc (see specification page 15) in which b is 2, c is 2, d is 3, P is H and R1 is C5 alkoxy residue; W is hydrogen; X is CH₃-(O-CH₂CH₂)₃-OH wherein X is attached through the O; V is tetraethylene glycol) was found to be free of the prior art. In accord with section 803.02 of the MPEP the search was then extended to other species and Rathore et al. (Journal of Polymer Science , Part A:Polymer Chemistry, 2000 v38(2) pages 352-366) was found as cited below. As such, the examination has been extended to the extent necessary to determine patentability of the Markush-type claim.

Claims 3-12,15-20 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/15/08.

Claims 1-2,13-14,21 are under consideration.

Specification

The objection remains from the previous office action.

The disclosure is objected to because of the following informalities:

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

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As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The section heading regarding the description of the drawings (see MPEP section 608.01f), for example, has not been included in the instant invention.

Appropriate correction is required.

Response to Arguments Specification Objection

Applicants argue that specification has been amended to provide headings as suggested.

Applicant's arguments filed 9/25/08 have been fully considered but they are not persuasive.

Although Applicants argue that specification has been amended to provide headings as suggested, the headings do not include a heading relating to a description of the drawings. It is

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noted that the previous office action expressly stated: The section heading regarding the description of the drawings (see MPEP section 608.01f), for example, has not been included in the instant invention.

Claim Rejections - 35 USC § 102

Since the claims have been amended and a new claim added, a new rejection adapted to the claims is recited below using the same reference as in the previous rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

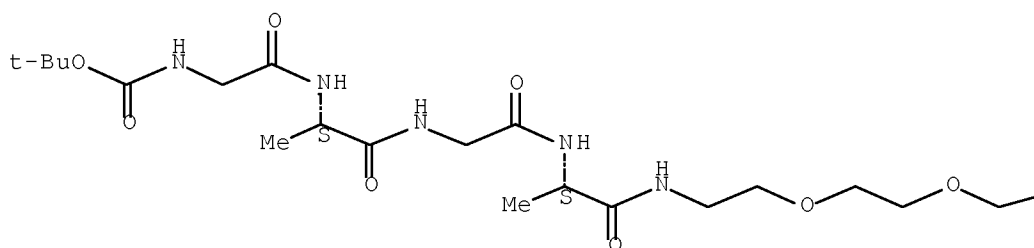
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

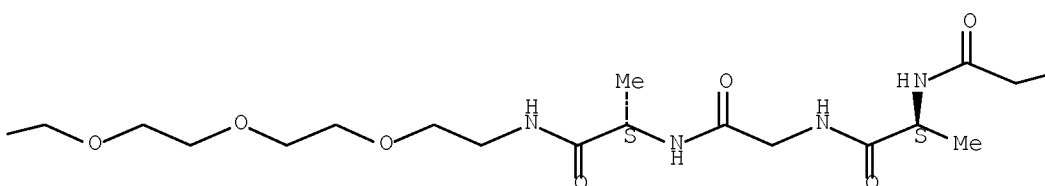
Claims 1-2,13-14,21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rathore et al. (Journal of Polymer Science , Part A:Polymer Chemistry, 2000 v38(2) pages 352-366).

Rathore teach copolymers containing polyethylene glycol segments and peptide segments (abstract). In scheme 1 (page 357) Rathore teach structure 6 (Boc-GAGA-HN(CH₂CH₂O)₅-CH₂CH₂NH-AGAG-Boc). It is noted that the structures of the amino acids of structure 6 are shown in chart 1 (page 353) and scheme 2 for example. Structure 6 of Rathore is:

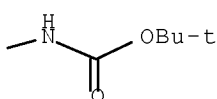
PAGE 1-A



PAGE 1-B



PAGE 1-C



In comparison to the instant invention the compound of Rathore is of formula Ia of claims 1,21 of the instant invention. Specifically, Z (A-HN(CH₂CH₂O)₅-CH₂CH₂NH-AGAG-Boc) includes the second alanine side chain residue and the polyethylene portion and second peptidic portion. As such, Z (A-HN(CH₂CH₂O)₅-CH₂CH₂NH-AGAG-Boc) exhibits at least two groups of formula IIa of the instant invention, specifically (CH₂CH₂O)_n and CH₂CH₂, where R₁ includes the second alanine side chain (i.e. CH(CH₃)C(O)NH which is a hydrocarbon

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residue with 1-10 carbon atoms with heteroatoms); n is 5. X and W (as part of the 2nd glycine residue) are hydrogen. V (Boc-GA) includes the first glycine residue and the side chain of the first alanine residue (i.e. a hydrocarbon residue which can contain hydrocarbons). Scheme 2 (page 357) shows that the NH residues, for example, can act in hydrogen bonding and as such the compound contains a binding group Y thus meeting the limitations on Y recited in claims 1,21 of the instant invention. The compound of Rathore meets the structural limitations of claims 1,21 of the instant invention.

It is noted that claim 2 recites that Y (which can be a part of any of V,W,X, and Z) is able to bind a wide range of groups. Although the office has no facility to test the binding capabilities of the compound of Rathore, due to the variety of groups contained in the compound of Rathore there is a reasonable basis that the compound meets the limitations of claim 2, absence evidence to the contrary. Further, the compound of Rathore meets the structural limitations of claim 1 so the functional properties recited are necessarily present absence evidence to the contrary.

Rathore teach (page 355 1st column last two paragraphs) the synthesis of structure 6 in solution so the compound is necessarily part of a composition thus meeting the structural limitations of claims 13-14 of the instant invention. It is noted that the recitation of 'diagnostic' in claim 14 does not result in a structural difference. As such Rathore meet the limitations of claims 1-2,13-14,21 of the instant invention.

Response to Arguments 102 rejection

Since the claims have been amended and a new claim added, a new rejection adapted to the claims is recited above using the same reference as in the previous rejection. Applicants arguments will be considered to the extent that they apply to the current rejection and claim set.

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Applicants argue that claim 1 differs from the prior art because the prior art only exhibits one group of the formula IIa.

Applicants argue that formula P5S and/or P5I differ from the instant invention because R1 has more than 10 carbon atoms.

Applicant's arguments filed 9/25/08 have been fully considered but they are not persuasive.

Although Applicants argue that claim 1 differs from the prior art because the prior art only exhibits one group of the formula IIa, it is noted that claim 1 states '...in that residues V, W, X and Z exhibit at least two groups of the formula (IIa)...'. Exhibiting groups of a formula is not the equivalent of comprising the formula. In other words, a group of a formula does not require that the group be the whole formula. The word 'group' is a term of art and one would recognize alcohols and nitriles, for example, as groups. For example, formula IIa includes $(\text{CH}_2\text{CH}_2\text{O})_n$ and CH_2CH_2 as distinct groups. There is no basis to limit the term group to mean only the whole of formula IIa. Section 2111 of the MPEP states that claims are to be given the broadest reasonable interpretation. Since the compound of Rathore contains the group $(\text{CH}_2\text{CH}_2\text{O})_n$ and the group CH_2CH_2 , the compound of Rathore necessarily exhibits two groups of formula IIa.

Although Applicants argue that formula P5S and/or P5I differ from the instant invention because R1 has more than 10 carbon atoms, the instant rejection is using structure 6 as shown in chart 1 (page 353 of Rathore). As such, the argument is not relevant to the instant rejection. Further, it is noted that open-ended language (compare MPEP 2111.03) is used in the instant

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claims so 'having' from 1 to 10 carbon atoms is not interpreted as 'consisting' of 1 to 10 carbon atoms.

Conclusion

Since the claims have been amended and a new claim added, a new rejection adapted to the claims is recited above using the same reference as in the previous rejection. Applicants amendments necessitated the rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-

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3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654